General

Guideline Title

Screening for vitamin D deficiency in adults: U.S. Preventive Services Task Force recommendation statement.

Bibliographic Source(s)

U.S. Preventive Services Task Force. Screening for vitamin D deficiency in adults: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med. 2015 Jan 20;162(2):133-40. [22 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

The U.S. Preventive Services Task Force (USPSTF) grades its recommendations (A, B, C, D, or I) and identifies the levels of certainty regarding net benefit (High, Moderate, and Low). The definitions of these grades can be found at the end of the "Major Recommendations" field.

Summary of Recommendation and Evidence

The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for vitamin D deficiency in asymptomatic adults. (I statement)

Clinical Considerations

Patient Population Under Consideration

This recommendation applies to community dwelling, nonpregnant adults aged 18 years or older who are seen in primary care settings and are not known to have signs or symptoms of vitamin D deficiency or conditions for which vitamin D treatment is recommended. This recommendation focuses on screening (that is, testing for vitamin D deficiency in asymptomatic adults and treating those who are found to have a deficiency), which is different from other USPSTF recommendation statements on supplementation (that is, recommending preventive medication for patients at increased risk for a specific negative health outcome, such as falls, regardless of whether they have a deficiency).

The USPSTF recognizes that there is no consensus on how to define vitamin D deficiency and does not endorse the use of a specific threshold to identify it. The evidence reviewed by the USPSTF used varying cut points. For the purposes of this recommendation statement, the term "vitamin D deficiency" is used to reflect evidence from study populations generally representing total serum 25-(OH)D levels of 75 nmol/L (30 ng/mL) or less or subpopulations of studies with levels less than 50 nmol/L (<20 ng/mL).

Suggestions for Practice Regarding the I Statement

Potential Preventable Burden

Given the lack of consensus on how to define and assess vitamin D deficiency, its precise prevalence estimates are difficult to determine. To collect precise estimates, it is necessary to establish accurate assay methods, an internationally recognized reference standard, and a specific cut point for defining vitamin D deficiency. Reported estimates of the prevalence of vitamin D deficiency vary widely depending on the period, cut point, study population, study design, and testing method. Estimates range from as low as 19% using a statistical modeling approach to as high as 77% based on National Health and Nutrition Examination Survey (NHANES) data from 2001 to 2004 (using a cut point of <75 nmol/L [<30 ng/mL]).

The effect of vitamin D levels on health outcomes is difficult to evaluate. Lower vitamin D levels have been reported to increase risk for fractures, falls, functional limitations, some types of cancer, diabetes, cardiovascular disease, depression, and death. However, observations of these associations are inconsistent and may vary by the cut point used to define low vitamin D levels and by subpopulation (defined by race or institutionalization). For example, African Americans have paradoxically lower reported rates of fractures despite having increased prevalence of low vitamin D levels than white persons.

If a threshold total serum 25-(OH)D level could be established to define vitamin D deficiency and if assays could be standardized, the goal of screening for vitamin D deficiency would be to identify and treat it before associated adverse clinical outcomes occur. However, current evidence is inadequate to determine whether screening for and treatment of asymptomatic low 25-(OH)D levels improve clinical outcomes in community-dwelling adults.

Potential Harms

Screening may misclassify persons with a vitamin D deficiency because of the uncertainty about the cut point for defining deficiency and the variability of available assays. Misclassification may result in over diagnosis (which may lead to nondeficient persons receiving unnecessary treatment) or under diagnosis (which may lead to deficient persons not receiving treatment).

A rare but potential harm of treatment with oral vitamin D is toxicity, which may lead to hypercalcemia, hyperphosphatemia, suppressed parathyroid hormone, and hypercalciuria. However, the 25-(OH)D level associated with toxicity (often defined as >500 nmol/L [>200 ng/mL]) is well above the level considered to be sufficient. Treatment with vitamin D plus calcium may also be associated with increased risk for kidney stones; vitamin D alone does not seem to increase this risk. In general, treatment with oral vitamin D does not seem to be associated with serious harms. Treatment with increased sun exposure (specifically ultraviolet B [UVB] radiation) may increase risk for skin cancer. Because of this concern, increased sun exposure is generally not recommended as treatment of vitamin D deficiency.

Costs

Several vitamin D testing methods are available; the cost of screening varies.

Current Practice

Testing rates for vitamin D levels seem to be increasing, despite the uncertainty about the definition of deficiency. Although estimates of screening rates in primary care settings are not available, a recent study evaluating data from the National Ambulatory Medical Care Survey and the National Hospital Ambulatory Medical Care Survey found that the annual rate of outpatient visits associated with a diagnosis code for vitamin D deficiency more than tripled between 2008 and 2010 (1177 visits per 100,000 population in 2010). In addition, according to a 2009 survey, total serum 25-(OH)D testing increased by at least 50% compared with the previous year in more than half of the clinical laboratories surveyed.

Assessment of Risk

Although there is not enough evidence to support screening for vitamin D deficiency, some evidence suggests factors that may increase risk for vitamin D deficiency. Persons with low vitamin D intake, decreased vitamin D absorption, and little or no sun exposure (for example, due to the winter season, high latitude, or physical sun avoidance) may be at increased risk for vitamin D deficiency. Obesity and darker skin pigmentation may also be associated with low levels of total serum 25-(OH)D, but whether these factors reflect vitamin D deficiency or increase the risk for adverse clinical outcomes is unclear. Obesity may allow for greater sequestration of vitamin D into adipose tissue; however, this vitamin D may still be bioavailable. Increased skin pigmentation reduces the skin's ability to produce vitamin D in response to UVB exposure. Prevalence rates of low total serum 25-(OH)D are 2 to 9 times higher in African Americans and 2 to 3 times higher in Hispanics than in white persons, yet the risk for fractures in African Americans is half that in white persons. Other factors, such as body composition and calcium economy, have been proposed to explain this paradox; however, a recent study suggests that although total serum 25-(OH)D levels in African Americans may be low, the concentration of bioavailable 25-(OH)D may not be. Some evidence suggests that older age and female sex may also be associated with increased

risk for vitamin D deficiency; however, these findings are inconsistent.

Screening Tests

Current vitamin D assays measure total serum 25-(OH)D levels to determine vitamin D status (that is, whether a person is considered to have or not have a deficiency). Many testing methods are available, including competitive protein binding, immunoassay, high-performance liquid chromatography, and combined high-performance liquid chromatography and mass spectrometry. However, the sensitivity and specificity of these tests are unknown because of the lack of studies that use an internationally recognized reference standard. Variability between assay methods and between laboratories using the same methods may range from 10% to 20%, and classification of samples as "deficient" or "nondeficient" may vary by 4% to 32%, depending on which assay is used. Another factor that may complicate interpretation is that 25-(OH)D may act as a negative acute-phase reactant, and its levels may decrease in response to inflammation. Lastly, whether common laboratory reference ranges are appropriate for all ethnic groups is unclear.

Treatment and Interventions

Oral vitamin D is most often used to treat vitamin D deficiency; other treatment options include increasing dietary vitamin D intake or UVB exposure. Commonly available forms of oral vitamin D include vitamin D_3 (cholecalciferol) and vitamin D_2 (ergocalciferol).

Additional Approaches to Prevention

According to the Institute of Medicine, daily dietary vitamin D intake of 600 IU in adults aged 18 to 70 years and 800 IU in adults older than 70 years should be sufficient to meet the needs of 97.5% of the adult population. UVB exposure may also increase vitamin D levels; however, several variables (such as the time of day, season, cloud cover, skin pigmentation, and sunscreen use) can affect the length of exposure needed to attain sufficient vitamin D levels. Sun exposure to prevent vitamin D deficiency is not generally recommended because it increases the risk for skin cancer associated with UVB radiation.

Useful Resources

The USPSTF has published recommendations on the use of vitamin D supplementation for the prevention of falls and fractures (see the National Guideline Clearinghouse [NGC] summary of the USPSTF guideline Vitamin D and calcium supplementation to prevent fractures in adults: U.S. Preventive Services Task Force recommendation statement) and vitamin supplementation for the prevention of cardiovascular disease or cancer (see the NGC summary of the USPSTF guideline Vitamin, mineral, and multivitamin supplements for the primary prevention of cardiovascular disease and cancer: U.S. Preventive Services Task Force recommendation statement). These recommendations differ from the current recommendation statement in that they address vitamin D supplementation in certain populations at high risk for falls, fractures, cardiovascular disease, or cancer without first determining a patient's vitamin D status.

Definitions:

What the U.S. Preventive Services Task Force (USPSTF) Grades Mean and Suggestions for Practice

Grade	Grade Definitions	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer/provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer/provide this service.
C	The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.	Offer/provide this service for selected patients depending on individual circumstances.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	Read the "Clinical Considerations" section of USPSTF Recommendation Statement (see the "Major Recommendations" field). If this service is offered, patients should understand the uncertainty about the balance of benefits and harms.

USPSTF Levels of Certainty Regarding Net Benefit

Definition: The USPSTF defines certainty as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.

Level of Certainty	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by factors such as: • The number, size, or quality of individual studies • Inconsistency of findings across individual studies • Limited generalizability of findings to routine primary care practice • Lack of coherence in the chain of evidence As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.
Low	The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of: • The limited number or size of studies • Important flaws in study design or methods • Inconsistency of findings across individual studies • Gaps in the chain of evidence • Findings not generalizable to routine primary care practice • A lack of information on important health outcomes More information may allow an estimation of effects on health outcomes.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Vitamin D deficiency

Guideline Category

Prevention

Risk Assessment

Screening

Clinical Specialty

Family Practice

Internal Medicine

Intended Users

Advanced Practice Nurses

Health Care Providers

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To summarize the current U.S. Preventive Services Task Force (USPSTF) recommendations and supporting scientific evidence on screening for vitamin D deficiency in adults

Target Population

Community-dwelling, nonpregnant adults aged 18 years or older who are seen in primary care settings and are not known to have signs or symptoms of vitamin D deficiency or conditions for which vitamin D treatment is recommended

Interventions and Practices Considered

Screening for vitamin D deficiency

Major Outcomes Considered

- Key Question 1: Is there direct evidence that screening for vitamin D deficiency results in improved health outcomes?
    a. Are there differences in screening efficacy between patient subgroups?
- Key Question 2: What are the harms of screening (for example, risk for procedure, false positives, or false negatives)?
- Key Question 3: Does treatment of vitamin D deficiency with vitamin D lead to improved health outcomes?
    a. Are there differences in efficacy between patient subgroups?
- Key Question 4: What are the adverse effects of treatment of vitamin D deficiency with vitamin D?
    a. Are there differences in adverse effects between patient subgroups?

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): A systematic evidence review was prepared by the Pacific Northwest Evidence-based Practice Center (EPC) for the U.S. Preventive Services Task Force (USPSTF) (see the "Availability of Companion Documents" field).

Data Sources and Searches

A research librarian searched Ovid MEDLINE (1946 through the third week of August 2014), Cochrane Central Register of Controlled Trials, and Cochrane Database of Systematic Reviews (through August 2014). Electronic searches were supplemented by reviewing reference lists of retrieved articles.

Study Selection

At least 2 reviewers independently evaluated each study to determine inclusion eligibility. For screening studies, they included randomized, controlled trials (RCTs) of screening for vitamin D deficiency versus no screening in healthy, asymptomatic adults (aged ≥18 years). For studies of the effectiveness of vitamin D treatment, the reviewers included RCTs of vitamin D treatment with or without calcium versus placebo or no treatment in vitamin D–deficient persons that reported health outcomes after at least 8 weeks of treatment. Because the Women's Health Initiative (WHI) is the largest RCT about vitamin D, they included data from nested case–control studies of WHI participants with known 25-(OH)D status.

The reviewers included English-language articles only and excluded studies published only as abstracts. They included studies conducted in the United States, Canada, United Kingdom, and other geographic settings generalizable to the United States. They excluded studies that specifically targeted populations with symptoms or conditions associated with vitamin D deficiency (for example, osteoporosis, history of nontraumatic fractures, or history of falls) or with medical conditions that increase a person's risk for deficiency (such as liver, kidney, or malabsorptive disease) because screening and treatment of vitamin D deficiency could be a component of medical management in these conditions. The summary of evidence search and selection is shown in Appendix Figure 2 of the systematic review.

Number of Source Documents

- Key Question 1: 0 studies
- Key Question 2: 0 studies
- Key Question 3: 17 studies
- Key Question 4: 24 studies

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Two investigators independently applied U.S. Preventive Services Task Force (USPSTF) criteria to rate the quality of each study as good, fair, or poor. See the "Description of the Methods Used to Analyze the Evidence" field for further information.

Methods Used to Analyze the Evidence

Meta-Analysis of Randomized Controlled Trials

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): A systematic evidence review was prepared by the Pacific Northwest Evidence-based Practice Center (EPC) for the U.S. Preventive Services Task Force (USPSTF) (see the "Availability of Companion Documents" field).

Data Abstraction and Quality Rating

One investigator abstracted details about the study design, patient population, setting, screening method, interventions, analysis, follow-up, and results. A second investigator reviewed data for accuracy. Two investigators independently applied USPSTF criteria to rate the quality of each study as good, fair, or poor. They resolved discrepancies through a consensus process. Investigators excluded from data synthesis studies rated as poor quality. Those studies had 1 or more fatal flaws, including inadequate randomization or lack of intervention fidelity combined with

postrandomization exclusions, high rates of withdrawals, and unclear randomization.

Data Synthesis and Analysis

The investigators assessed the aggregate internal validity (quality) of the body of evidence for each key question (good, fair, or poor) using methods developed by the USPSTF on the basis of the number, quality, and size of studies; consistency of results; and directness of evidence.

The investigators conducted meta-analyses to calculate risk ratios (RRs) using the DerSimonian–Laird random-effects model (Review Manager, version 5.2; Cochrane Collaboration). Analyses were based on total follow-up (including time after discontinuation of vitamin D treatment). For falls per person, they calculated incidence rate ratios and assumed equal mean length of follow-up across treatment groups if these data were not reported. For analyses with between-study heterogeneity, the investigators conducted sensitivity analyses using profile likelihood random-effects models. Rate ratio analysis and analyses using the profile likelihood random-effects model were done with Stata, version 12.0 (StataCorp). They performed sensitivity analyses restricted to randomized controlled trials (RCTs), excluding the Women's Health Initiative (WHI) subanalyses, and used odds ratios rather than RRs.

The investigators assessed statistical heterogeneity using the chi-square test and I^2 statistic. For all analyses, they stratified results by serum baseline 25-(OH)D level (<50 nmol/L [<20 ng/mL] vs. ≤75 nmol/L [≤30 ng/mL]). They performed additional analyses in which trials were stratified by institutionalized status, treatment regimen (vitamin D alone [vitamin D vs. placebo or no treatment, or vitamin D plus calcium vs. calcium alone] or vitamin D combined with calcium [vitamin D plus calcium vs. placebo or no treatment]), vitamin D dose (≤400 vs. >400 IU/d), duration of follow-up (≤12 vs. >12 months), and participant mean age (≤70 vs. >70 years).

Methods Used to Formulate the Recommendations

Balance Sheets

Expert Consensus

Description of Methods Used to Formulate the Recommendations

The U.S. Preventive Services Task Force (USPSTF) systematically reviews the evidence concerning both the benefits and harms of widespread implementation of a preventive service. It then assesses the certainty of the evidence and the magnitude of the benefits and harms. On the basis of this assessment, the USPSTF assigns a letter grade to each preventive service signifying its recommendation about provision of the service (see Table below). An important, but often challenging, step is determining the balance between benefits and harms to estimate "net benefit" (that is, benefits minus harms).

Table 1. U.S. Preventive Services Task Force Recommendation Grid*

Certainty of Net Benefit	Magnitude of Net Benefit			
	Substantial	Moderate	Small	Zero/Negative
High	A	B	C	D
Moderate	B	B	C	D
Low	Insufficient			

**A, B, C, D*, and *I (Insufficient)* represent the letter grades of recommendation or statement of insufficient evidence assigned by the USPSTF after assessing certainty and magnitude of net benefit of the service (see the "Rating Scheme for the Strength of the Recommendations" field).

The overarching question that the USPSTF seeks to answer for every preventive service is whether evidence suggests that provision of the service would improve health outcomes if implemented in a general primary care population. For screening topics, this standard could be met by a large randomized, controlled trial (RCT) in a representative asymptomatic population with follow-up of all members of both the group "invited for screening" and the group "not invited for screening."

Direct RCT evidence about screening is often unavailable, so the USPSTF considers indirect evidence. To guide its selection of indirect evidence, the USPSTF constructs a "chain of evidence" within an analytic framework. For each key question, the body of pertinent literature is critically appraised, focusing on the following 6 questions:

1. Do the studies have the appropriate research design to answer the key question(s)?
2. To what extent are the existing studies of high quality? (i.e., what is the internal validity?)
3. To what extent are the results of the studies generalizable to the general U.S. primary care population and situation? (i.e., what is the external validity?)
4. How many studies have been conducted that address the key question(s)? How large are the studies? (i.e., what is the precision of the evidence?)
5. How consistent are the results of the studies?
6. Are there additional factors that assist the USPSTF in drawing conclusions (e.g., presence or absence of dose–response effects, fit within a biologic model)?

The next step in the USPSTF process is to use the evidence from the key questions to assess whether there would be net benefit if the service were implemented. In 2001, the USPSTF published an article that documented its systematic processes of evidence evaluation and recommendation development. At that time, the USPSTF's overall assessment of evidence was described as good, fair, or poor. The USPSTF realized that this rating seemed to apply only to how well studies were conducted and did not fully capture all of the issues that go into an overall assessment of the evidence about net benefit. To avoid confusion, the USPSTF has changed its terminology. Whereas individual study quality will continue to be characterized as good, fair, or poor, the term certainty will now be used to describe the USPSTF's assessment of the overall body of evidence about net benefit of a preventive service and the likelihood that the assessment is correct. Certainty will be determined by considering all 6 questions listed above; the judgment about certainty will be described as high, moderate, or low.

In making its assessment of certainty about net benefit, the evaluation of the evidence from each key question plays a primary role. It is important to note that the USPSTF makes recommendations for real-world medical practice in the United States and must determine to what extent the evidence for each key question—even evidence from screening RCTs or treatment RCTs—can be applied to the general primary care population. Frequently, studies are conducted in highly selected populations under special conditions. The USPSTF must consider differences between the general primary care population and the populations studied in RCTs and make judgments about the likelihood of observing the same effect in actual practice.

It is also important to note that one of the key questions in the analytic framework refers to the potential harms of the preventive service. The USPSTF considers the evidence about the benefits and harms of preventive services separately and equally. Data about harms are often obtained from observational studies because harms observed in RCTs may not be representative of those found in usual practice and because some harms are not completely measured and reported in RCTs.

Putting the body of evidence for all key questions together as a chain, the USPSTF assesses the certainty of net benefit of a preventive service by asking the 6 major questions listed above. The USPSTF would rate a body of convincing evidence about the benefits of a service that, for example, derives from several RCTs of screening in which the estimate of benefits can be generalized to the general primary care population as "high" certainty (see the "Rating Scheme for the Strength of Recommendations" field). The USPSTF would rate a body of evidence that was not clearly applicable to general practice or has other defects in quality, research design, or consistency of studies as "moderate" certainty. Certainty is "low" when, for example, there are gaps in the evidence linking parts of the analytic framework, when evidence to determine the harms of treatment is unavailable, or when evidence about the benefits of treatment is insufficient. Table 4 in the methodology document listed below (see "Availability of Companion Documents" field) summarizes the current terminology used by the USPSTF to describe the critical assessment of evidence at all 3 levels: individual studies, key questions, and overall certainty of net benefit of the preventive service.

Sawaya GF, Guirguis-Blake J, LeFevre M, Harris R, Petitti D; U.S. Preventive Services Task Force. Update on the methods of the U.S. Preventive Services Task Force: estimating certainty and magnitude of net benefit. Ann Intern Med. 2007;147(12):871-875. [5 references].

I Statements

For I statements, the USPSTF has a plan to commission its Evidence-based Practice Centers to collect information in 4 domains pertinent to clinical decisions about prevention and to report this information routinely. This plan is described in the paper: Petitti DB et al. Update on the methods of the U.S. Preventive Services Task Force: insufficient evidence. Ann Intern Med. 2009;150:199-205. www.annals.org .

The first domain is potential preventable burden of suffering from the condition. When evidence is insufficient, provision of an intervention designed to prevent a serious condition (such as dementia) might be viewed more favorably than provision of a service designed to prevent a condition that does not cause as much suffering (such as rash). The USPSTF recognized that "burden of suffering" is subjective and involves judgment. In clinical settings, it should be informed by patient values and concerns.

The second domain is potential harm of the intervention. When evidence is insufficient, an intervention with a large potential for harm (such as

major surgery) might be viewed less favorably than an intervention with a small potential for harm (such as advice to watch less television). The USPSTF again acknowledges the subjective nature and the difficulty of assessing potential harms: for example, how bad is a "mild" stroke?

The third domain is cost—not just monetary cost, but opportunity cost, in particular the amount of time a provider spends to provide the service, the amount of time the patient spends to partake of it, and the benefits that might derive from alternative uses of the time or money for patients, clinicians, or systems. Consideration of clinician time is especially important for preventive services with only insufficient evidence because providing them could "crowd out" provision of preventive services with proven value, services for conditions that require immediate action, or services more desired by the patient. For example, a decision to routinely inspect the skin could take up the time available to discuss smoking cessation, or to address an acute problem or a minor injury that the patient considers important.

The fourth domain is current practice. This domain was chosen because it is important to clinicians for at least 2 reasons. Clinicians justifiably fear that not doing something that is done on a widespread basis in the community may lead to litigation. More important, addressing patient expectations is a crucial part of the clinician–patient relationship in terms of building trust and developing a collaborative therapeutic relationship. The consequences of not providing a service that is neither widely available nor widely used are less serious than not providing a service accepted by the medical profession and thus expected by patients. Furthermore, ingrained care practices are difficult to change, and efforts should preferentially be directed to changing those practices for which the evidence to support change is compelling.

Although the reviewers did not explicitly recognize it when these domains were chosen, the domains all involve consideration of the potential consequences—for patients, clinicians, and systems—of providing or not providing a service. Others writing about medical decision making in the face of uncertainty have suggested that the consequences of action or inaction should play a prominent role in decisions.

Rating Scheme for the Strength of the Recommendations

What the U.S. Preventive Services Task Force (USPSTF) Grades Mean and Suggestions for Practice

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C	The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.	Offer/provide this service for selected patients depending on individual circumstances.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality or conflicting, and the balance of benefits and harms cannot be determined.	Read the "Clinical Considerations" section of USPSTF Recommendation Statement (see the "Major Recommendations" field). If offered, patients should understand the uncertainty about the balance of benefits and harms.

USPSTF Levels of Certainty Regarding Net Benefit

Definition: The USPSTF defines certainty as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.

Level of Certainty	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.

Level of Certainty	Description
Moderate	The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by factors such as: • The number, size, or quality of individual studies • Inconsistency of findings across individual studies • Limited generalizability of findings to routine primary care practice • Lack of coherence in the chain of evidence As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.
Low	The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of: • The limited number or size of studies • Important flaws in study design or methods • Inconsistency of findings across individual studies • Gaps in the chain of evidence • Findings not generalizable to routine primary care practice • A lack of information on important health outcomes More information may allow an estimation of effects on health outcomes.

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Comparison with Guidelines from Other Groups

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Peer Review. Before the U.S. Preventive Services Task Force (USPSTF) makes its final determinations about recommendations on a given preventive service, the Evidence-based Practice Center and the Agency for Healthcare Research and Quality send a draft evidence review to 4 to 6 external experts and to Federal agencies and professional and disease-based health organizations with interests in the topic. The experts are asked to examine the review critically for accuracy and completeness and to respond to a series of specific questions about the document. The draft evidence review is also posted on the USPSTF Web site for public comment. After assembling these external review comments and documenting the proposed response to key comments, the topic team presents this information to the USPSTF in memo form. In this way, the USPSTF can consider these external comments before it votes on its recommendations about the service. Draft recommendation statements are then circulated for comment among reviewers representing professional societies, voluntary organizations, and Federal agencies, as well as posted on the USPSTF Web site for public comment. These comments are discussed before the final recommendations are confirmed.

Response to Public Comment. A draft version of this recommendation statement was posted for public comment on the USPSTF Web site from 24 June to 21 July 2014. Several comments requested that the scope of the recommendation be expanded to include special populations, such as those with bone, endocrine, and immune conditions. The USPSTF clarified the recommendation to better explain to which populations it applies and why other populations were not included. A few comments also requested information on risk assessment tools that could be used to stratify patients into high versus low risk for vitamin D deficiency before testing. The systematic review did not evaluate the evidence on risk assessment tools; however, the USPSTF may consider looking at this information in future updates of the topic. Comments also provided information on additional factors that complicate interpretation of vitamin D tests; the USPSTF added discussion of these factors to the Clinical Considerations and Discussion sections.

Comparison with Guidelines from Other Groups. Recommendations for screening from the following groups were discussed: the American Academy of Family Physicians, the Endocrine Society, the American Congress of Obstetricians and Gynecologists, the American Geriatric

Society, the National Osteoporosis Foundation, and the Institute of Medicine.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Benefits of Detection and Early Treatment

The U.S. Preventive Services Task Force (USPSTF) found no studies that evaluated the direct benefit of screening for vitamin D deficiency in adults. The USPSTF found adequate evidence that treatment of asymptomatic vitamin D deficiency has no benefit on cancer, type 2 diabetes mellitus, risk for death in community-dwelling adults, and risk for fractures in persons not selected on the basis of being at high risk for fractures. The USPSTF found inadequate evidence on the benefit of treatment of asymptomatic vitamin D deficiency on other outcomes, including psychosocial and physical functioning. Although the evidence is adequate for a few limited outcomes, the overall evidence on the early treatment of asymptomatic, screen-detected vitamin D deficiency in adults to improve overall health outcomes is inadequate.

Potential Harms

Harms of Detection and Early Treatment

The U.S. Preventive Services Task Force (USPSTF) found no studies that evaluated the direct harms of screening for vitamin D deficiency. The USPSTF found adequate evidence that the harms of treatment of vitamin D deficiency are small to none. No studies reporting on the harms of treatment of vitamin D deficiency identified a significant increase in total adverse events, hypercalcemia, kidney stones, or gastrointestinal symptoms.

Qualifying Statements

Qualifying Statements

- The U.S. Preventive Services Task Force (USPSTF) makes recommendations about the effectiveness of specific clinical preventive services for patients without related signs or symptoms.
- It bases its recommendations on the evidence of both the benefits and harms of the service and an assessment of the balance. The USPSTF does not consider the costs of providing a service in this assessment.
- The USPSTF recognizes that clinical decisions involve more considerations than evidence alone. Clinicians should understand the evidence but individualize decision making to the specific patient or situation. Similarly, the USPSTF notes that policy and coverage decisions involve considerations in addition to the evidence of clinical benefits and harms.
- Recommendations made by the USPSTF are independent of the U.S. government. They should not be construed as an official position of the Agency for Healthcare Research and Quality (AHRQ) or the U.S. Department of Health and Human Services.

Implementation of the Guideline

Description of Implementation Strategy

The experiences of the first and second U.S. Preventive Services Task Force (USPSTF), as well as that of other evidence-based guideline efforts, have highlighted the importance of identifying effective ways to implement clinical recommendations. Practice guidelines are relatively weak tools for changing clinical practice when used in isolation. To effect change, guidelines must be coupled with strategies to improve their acceptance and feasibility. Such strategies include enlisting the support of local opinion leaders, using reminder systems for clinicians and patients, adopting standing orders, and audit and feedback of information to clinicians about their compliance with recommended practice.

In the case of preventive services guidelines, implementation needs to go beyond traditional dissemination and promotion efforts to recognize the added patient and clinician barriers that affect preventive care. These include clinicians' ambivalence about whether preventive medicine is part of their job, the psychological and practical challenges that patients face in changing behaviors, lack of access to health care or of insurance coverage for preventive services for some patients, competing pressures within the context of shorter office visits, and the lack of organized systems in most practices to ensure the delivery of recommended preventive care.

Dissemination strategies have changed dramatically in this age of electronic information. While recognizing the continuing value of journals and other print formats for dissemination, the USPSTF will make all its products available through its Web site . The combination of electronic access and extensive material in the public domain should make it easier for a broad audience of users to access USPSTF materials and adapt them for their local needs. Online access to USPSTF products also opens up new possibilities for the appearance of the annual, pocket-size Guide to Clinical Preventive Services.

To be successful, approaches for implementing prevention have to be tailored to the local level and deal with the specific barriers at a given site, typically requiring the redesign of systems of care. Such a systems approach to prevention has had notable success in established staff-model health maintenance organizations, by addressing organization of care, emphasizing a philosophy of prevention, and altering the training and incentives for clinicians. Staff-model plans also benefit from integrated information systems that can track the use of needed services and generate automatic reminders aimed at patients and clinicians, some of the most consistently successful interventions. Information systems remain a major challenge for individual clinicians' offices, however, as well as for looser affiliations of practices in network-model managed care and independent practice associations, where data on patient visits, referrals, and test results are not always centralized.

Implementation Tools

Foreign Language Translations

Mobile Device Resources

Patient Resources

Pocket Guide/Reference Cards

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

U.S. Preventive Services Task Force. Screening for vitamin D deficiency in adults: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med. 2015 Jan 20;162(2):133-40. [22 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2015 Jan 20

Guideline Developer(s)

U.S. Preventive Services Task Force - Independent Expert Panel

Guideline Developer Comment

The U.S. Preventive Services Task Force (USPSTF) is a federally-appointed panel of independent experts. Conclusions of the USPSTF do not necessarily reflect policy of the U.S. Department of Health and Human Services or its agencies.

Source(s) of Funding

The U.S. Preventive Services Task Force (USPSTF) is an independent, voluntary body. The U.S. Congress mandates that the Agency for Healthcare Research and Quality support the operations of the USPSTF.

Guideline Committee

U.S. Preventive Services Task Force (USPSTF)

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**Members of the USPSTF at the time this recommendation was finalized. For a list of current Task Force members, go to*

www.uspreventiveservicestaskforce.org/Page/Name/our-members.

Financial Disclosures/Conflicts of Interest

The U.S. Preventive Services Task Force (USPSTF) has an explicit policy concerning conflict of interest. All members disclose at each meeting if they have a significant financial, professional/business, or intellectual conflict for each topic being discussed. USPSTF members with conflicts may be recused from discussing or voting on recommendations about the topic in question.

Potential Conflicts of Interest: Dr. Gillman reports royalties from Cambridge University Press and UpToDate outside the submitted work. Authors not named here have disclosed no conflicts of interest. Authors followed the policy regarding conflicts of interest described at www.uspreventiveservicestaskforce.org/Page/Name/methods-and-processes. Disclosures can be viewed at www.acponline.org/authors/icmje/ConflictOfInterestForms.do?msNum=M14-2450.

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Electronic copies: Available from the Annals of Internal Medicine Web site.

Availability of Companion Documents

The following are available:

Evidence Reviews:

- LeBlanc ES, Zakher B, Daeges M, Pappas M, Chou R. Screening for vitamin D deficiency: a systematic review for the U.S. Preventive Services Task Force. Ann Intern Med. 2015 Jan 20;162(1):109-122.
- LeBlanc E, Chou R, Zakher B, Daeges M, Pappas M. Screening for vitamin D deficiency: systematic review for the U.S. Preventive Services Task Force recommendation. Evidence Synthesis No. 119. AHRQ Publication No. 13-05183-EF-1. Rockville (MD): Agency for Healthcare Research and Quality; 2014 Nov. 217 p.

Electronic copies: Available from the U.S. Preventive Services Task Force (USPSTF) Web site.

Background Articles:

- Barton MB et al. How to read the new recommendation statement: methods update from the U.S. Preventive Services Task Force. Ann Intern Med 2007;147:123-127.
- Guirguis-Blake J et al. Current processes of the U.S. Preventive Services Task Force: refining evidence-based recommendation development. Ann Intern Med 2007;147:117-122.
- Sawaya GF et al. Update on the methods of the U.S. Preventive Services Task Force: estimating certainty and magnitude of net benefit. Ann Intern Med 2007;147:871-875.
- Petitti DB et al. Update on the methods of the U.S. Preventive Services Task Force: insufficient evidence. Ann Intern Med. 2009;150:199-205.

Electronic copies: Available from the USPSTF Web site.

The following are also available:

- Vitamin D deficiency: screening. Clinical summary of the U.S. Preventive Services Task Force (USPSTF) recommendation. 2014. 1 p. Electronic copies: Available from the USPSTF Web site.
- A continuing medical education (CME) activity is available from the Annals of Internal Medicine Web site.

- The guide to clinical preventive services, 2014. Recommendations of the U.S. Preventive Services Task Force. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2014. 144 p. Electronic copies: Available from the AHRQ Web site.

The Electronic Preventive Services Selector (ePSS) is an application designed to provide primary care clinicians and health care teams timely decision support regarding appropriate screening, counseling, and preventive services for their patients. It is based on the current, evidence-based recommendations of the USPSTF and can be searched by specific patient characteristics, such as age, sex, and selected behavioral risk factors.

Patient Resources

The following are available:

- Screening for vitamin D deficiency in adults: U.S. Preventive Services Task Force recommendation statement. Understanding task force recommendations. Rockville (MD): U.S. Preventive Services Task Force. Consumer fact sheet. 2014 Nov. 4 p. Electronic copies: Available from the U.S. Preventive Services Task Force (USPSTF) Web site.
- Screening for vitamin D deficiency in adults: U.S. Preventive Services Task Force recommendation statement. Summaries for patients. Ann Intern Med. 2015 Jan 20;162(1):133-140. Electronic copies: Available from the Annals of Internal Medicine Web site.
- Women: stay healthy at any age. 2014 update. Rockville (MD): Agency for Healthcare Research and Quality. AHRQ Pub. No. 14-IP007-A. 2014 Mar. 5 p. Electronic copies: Available in English and Spanish from the Agency for Healthcare Research and Quality (AHRQ) Web site.
- Men: stay healthy at any age. 2014 update. Rockville (MD): Agency for Healthcare Research and Quality. AHRQ Pub. No. 14-IP006-A. 2014 Mar. 5 p. Electronic copies: Available in English and Spanish from the AHRQ Web site.
- Women: stay healthy at 50+. 2014 update. Rockville (MD): Agency for Healthcare Research and Quality. AHRQ Pub. No. 14-IP002-A. 2014 Mar. 5 p. Electronic copies: Available in English and Spanish from the AHRQ Web site.
- Men: stay healthy at 50+. 2014 update. Rockville (MD): Agency for Healthcare Research and Quality. AHRQ Pub. No. 14-IP009-A. 2014 Mar. 5 p. Electronic copies: Available in English and Spanish from the AHRQ Web site.

Print copies: Available in English and Spanish from the AHRQ Publications Clearinghouse. For more information, go to http://www.ahrq.gov/research/publications/index.html or call 1-800-358-9295 (U.S. only).

Myhealthfinder is a tool that provides personalized recommendations for clinical preventive services specific to the user's age, gender, and pregnancy status. It features evidence-based recommendations from the USPSTF and is available at www.healthfinder.gov.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

This NGC summary was completed by ECRI Institute on February 5, 2015. The information was verified by the guideline developer on March 13, 2015.

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